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AVAILABILITY OF THE PHARMACEUTICAL SERVICE AS A PUBLIC HEALTH PROTECTION CORRELATE – THE LEGAL APPROACH¹

DOSTĘPNOŚĆ USŁUGI FARMACEUTYCZNEJ JAKO KORELAT OCHRONY ZDROWIA PUBLICZNEGO – UJĘCIE PRAWNE

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Summary: The functioning of the pharmacy market in Poland is subject to strict statutory regulation. In striving to ensure the widest availability of services provided by generally accessible pharmacies to patients, the legislator introduced a solution consisting in granting county ('powiat') councils the power to issue local acts of law regarding the establishment of working hours of generally accessible pharmacies locally. Compliance with this obligation, however, faces various difficulties on the part of both pharmacies and self-government bodies, which negatively affects the effectiveness of the existing solution. The subject of this article is the assessment of existing legal solutions in the discussed area, together with a review of the proposed statutory changes developed by pharmacies self-government and the Association of Polish Counties ('powiat').

Keywords: generally accessible pharmacy, pharmacist, pharmaceutical law, public health.

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Streszczenie: Funkcjonowanie rynku aptekarskiego w Polsce podlega ścisłej regulacji ustawowej. Dążąc do zapewnienia jak najszerzej dostępności usług świadczonych przez apteki ogólnodostępne dla pacjentów, ustawodawca wprowadził rozwiązanie polegające na przyznaniu radom powiatów uprawnienia do wydawania aktów prawa miejscowego w przedmiocie ustalenia rozkładów godzin pracy aptek ogólnodostępnych na obszarze powiatów. Wypełnianie tego obowiązku napotyka jednak różne trudności ze strony zarówno aptek, jak i organów samorządu, co wpływa negatywnie na efektywność rozwiązania. Przedmiotem artykułu jest ocena istniejących rozwiązań prawnych w omawianym zakresie i omówienie proponowanych zmian ustawowych opracowanych przez samorząd aptekarski i Związek Powiatów Polskich.

Słowa kluczowe: apteka ogólnodostępna, farmaceuta, prawo farmaceutyczne, zdrowie publiczne.

1. Introduction

Conducting pharmacy activities is a special type of economic activity subject to the priority of achieving the public goal in the form of public health protection. A generally accessible pharmacy is not only an enterprise subject to market trading rules on the basis of the freedom of economic activity, but in its primary and superior function it is a public health protection facility. Conducting pharmacy activities remains, therefore, determined by a kind of dualism of goals, i.e. the implementation of the economic goal and the public goal, while maintaining the absolute priority of public health protection. The issue of the availability of the pharmaceutical service as a correlate for the protection of public health and the patient's right to receive medicine is a part of the context of the indicated particular perspective of conducting pharmacy activities.

In accordance with art. 86 of the Act of 6 September 2001, Pharmaceutical Law (consolidated text, JoL of 2019, item 499, as amended, hereinafter: a.p.l. or Pharmaceutical Law), generally accessible pharmacies are public health facilities where authorized persons provide pharmaceutical services to the public consisting of:

- dispensing medicinal products and medical devices,
- preparation of prescription drugs,
- preparation of pharmacy medicines,
- providing information on medicinal products and medical devices.

The above activity finds special support in art. 68 of the Constitution of the Republic of Poland (JoL of 1997, No. 78, item 483, as amended, hereinafter referred to as: CRP), according to which the right to health protection belongs to one of the basic civil rights, and its correlate is the obligation of the public authorities to implement specific tasks of public health protection. Therefore, providing patients with full and permanent access to pharmaceutical services is an important area of state authority. The tasks of the state administration bodies include not only creating the appropriate system, but also ensuring the efficiency and effectiveness of its

functioning. Only the total fulfilment of these conditions will allow for achieving a lawful goal, which is to enable citizens to implement the constitutional right to health protection.

The purpose of this article is to analyse the legal solutions determining the availability of a pharmaceutical service as a correlate for public health protection, with particular emphasis on the assessment of the administrative and legal solutions determining the indicated availability in the scope of work organization and pharmacy management.

The article uses the method of legal regulation analysis and the descriptive method.

2. Enacting the distribution of working hours of generally accessible pharmacies – legal basis

Pursuant to the content of art. 94 par. 2 a.p.l. the distribution of the working hours of generally accessible pharmacies in a given area, is determined by the resolution of the county ('powiat') council after seeking the opinion of the commune heads (mayors, city presidents) of communes from that area and the pharmacy self-government. In accordance with art. 94 par. 1 a.p.l., this distribution should be tailored to the needs of the population and ensure the availability of benefits also at night, on Sundays, holidays and other non-working days.

The above provisions introduce the principle that the determination of the working hours of generally accessible pharmacies is to a significant extent governed by public law, and therefore is not the sole competence of the owners or managers of pharmacies. It is therefore a significant limitation of the freedom of economic activity of the entrepreneur running the pharmacy. It should be stipulated that other units conducting retail drug trade, such as pharmacy outlets and non-pharmacy trading units, are not subject to similar regulations [Olszewski (ed.) 2016, p. 952].

The indicated mechanism of the intervention of local government bodies in the organization of pharmacy work is often a source of significant problems in the functioning of many generally accessible pharmacies. The adopted legal solution turns out to be problematic both for the local self-government bodies from the point of view of fulfilling their statutory tasks, as well as the entrepreneurs running a pharmacy, primarily due to labour and economic conditions.

For some generally accessible pharmacies, the need to work at night and on public holidays is a significant financial burden which is not compensated by the proceeds from the sale of the range of products in these periods, including increased payments for sales at night, referred to in art. 94 par. 3 point 1 of a.p.l. In addition to the strictly financial issue, the necessity to work in a generally accessible pharmacy at night and on public holidays is also associated with the need to ensure the presence of professional staff in the pharmacy, which, especially in the case of smaller pharmacies, raises significant staffing problems.

The current legal status in this scope also raises significant doubts in the context of the effectiveness of the implementation of public tasks by local self-government bodies. According to the content of the abovementioned art. 94 par. 2 a.p.l., the county councils are obliged to issue an act of local law specifying the distribution of working hours of generally accessible pharmacies in accordance with the local jurisdiction. At the same time, however, no other provision of the Act gives the local legal authorities the possibility of verifying or enforcing the implementation of the adopted schedule of hours of work by the generally accessible pharmacies covered by it. County authorities are therefore deprived of an effective legal remedy that allows them to supervise and control the practical implementation of their obligation for the organization of the public health protection system, of which generally accessible pharmacies are an important component.

3. Practical aspects of implementing the obligation to perform duties by generally accessible pharmacies

Conducting economic activities in the form of generally accessible pharmacies is covered by a special legal structure due to the fact that the pharmacy combines both the features of an enterprise and a public health care facility. Since the issues of the proper organization of health care are among particularly important public tasks, the activity of pharmacies is a regulated activity within the meaning of art. 37 of the Act of March 6, 2018, Entrepreneurs Law (consolidated text, JoL of 2019, item 1292, as amended, hereinafter: Entrepreneurs Law), according to which conducting economic activity in areas of particular importance due to the security of the state or citizens or other important public interest requires a license only if this activity cannot be carried out as free or after obtaining an entry in the register of regulated activities or a permit. The indicated dualism of the objectives of the pharmacy activity and the legal and formal consequences arising from it should be thoroughly analysed by each entity already at the stage of planning to conduct business in the form of running a pharmacy.

However, taking into account that, in addition to the aforementioned public law sphere related to the performance of tasks that are particularly important from the point of view of health protection, entities operating generally accessible pharmacies are entrepreneurs (and as such are subject to the obligations provided for in this respect by law), it should be noted that in art. 3 of the Entrepreneurs Law, one of the features characterizing economic activity is its commercial nature. The concept of 'earnings' within the meaning of the Entrepreneurs Law should be identified with the concept of 'income' within the meaning of tax law, and therefore, in accordance with art. 9 par. 2 of the Act of 26 July 1991 on personal income tax (consolidated text JoL of 2019, item 1387, as amended), with a surplus of total revenues from the source of revenues over costs achieved as part of the economic activity in the tax year.

Representatives of the pharmacy self-government have often indicated that the need to be on duty at night and on public holidays in accordance with the schedule

adopted by the county councils is completely unprofitable for many pharmacies from the point of view of economic calculation (Grosman, 2018). This situation consists of two basic factors. First, pursuant to the content of art. 92 a.p.l., a pharmacist should be present during pharmacy opening hours, referred to in art. 88 par 1 a.p.l. In light of the judgment of the Supreme Administrative Court of 20.02.2019, there is currently no doubt that the pharmacist referred to in art. 92 a.p.l. is the head of a pharmacy or possibly another pharmacist who, in light of the provisions of the Pharmaceutical Law, is entitled to act as pharmacy manager (Judgment of the Supreme Administrative Court of 20.02.2019...). In the justification of the cited judgment, the Supreme Administrative Court stated that “art. 92 a.p.l. stipulating that a pharmacist should be present during pharmacy opening hours, as referred to in art. 88 par. 1 a.p.l. refers not to the general concept of the pharmacist arising from the provision of art. 2b par. 1 point 1, 2 and 5-7 of the Act on Pharmaceutical Chambers, but to the one defined in art. 88 par. 1 a.p.l. the concept of a pharmacist responsible for operating a pharmacy, i.e. one who meets the additional requirements in terms of seniority specified in art. 88 par. 2 a.p.l.” (Judgment of the Supreme Administrative Court of 20.02.2019...).

Similar requirements also apply to the operation of generally accessible pharmacies at night and on public holidays. As at this time and on those days, the owner of the pharmacy is obliged to ensure the presence of appropriate professional staff in the pharmacy, it is necessary for the owner of the pharmacy to incur additional costs related to due remuneration. However, in the case of smaller and individual pharmacies, i.e. those not belonging to the structure of the pharmacy network, and in which the pharmacy manager is in practice often the owner of the pharmacy itself, who is also the same and often the only MA in Pharmacy employed there, the implementation of the indicated requirements for the organization of the pharmacy work is associated with performing professional duties for a significantly extended working time. According to representatives of the pharmacy community, this may lead to a specific, at least temporary, decrease in the quality of activities performed and services rendered. Secondly, the information provided by representatives of the pharmacy community shows that in the vast majority of cases the amount of revenue from the sale of medicinal products and other assortment of generally accessible pharmacies, especially at night, is relatively low and does not cover the costs of operating the pharmacy at that time (Politowicz, 2017). It should be pointed out here that established on the basis of art. 94 par. 3 a.p.l. , i.e. pursuant to § 1 of the Regulation of the Minister of Health of 14 June 2002 on the maximum amount of extra payments charged by a pharmacy for the dispatch of medicinal products at night and specification of a group of medicinal products for which no fee is charged at night (consolidated text JoL of 2014, item 765), the maximum amount of extra payments charged by a pharmacy for dispatching medicines at night, regardless of the number of medicinal products issued or prescriptions carried out, is currently PLN 3.20. In accordance with § 2 of the abovementioned regulation, the indicated fee is not

charged for the issue of narcotic drugs, antibiotics and medicinal products on prescription, on which the annotation 'cito' or other equivalent is placed, if the prescription is carried out at night on the day of its issue or the next day.

The pharmacy community also argues that the issue of a local legal act by the local council in the form of a resolution containing the work schedule of generally accessible pharmacies constitutes a public interference with the constitutional principle of establishment of freedom. According to the content of art. 20 CRP, freedom of economic activity is the basis of the economic system of the Republic of Poland. In addition, in accordance with art. 2 Entrepreneurs Law, taking up the pursuit and termination of economic activity is freely available for everyone on equal rights. The pharmacy self-government also indicates the necessity and need to synchronize the distribution of working hours in specific counties with the facilities functioning in this area providing 24-hour medical assistance (Lower Silesian Pharmaceutical Chamber, 2016). In particular, attention is drawn to the lack of correlation in determining the duty of pharmacies, which is reflected in situations in which generally accessible pharmacies located in places where there are no facilities providing 24-hour medical assistance, are designated for night duty. In the assessment of the pharmacy self-government, it is obvious that the local residents, if it is necessary to obtain medical assistance, will first go to the health service and then use the services of pharmacies located in the place where they receive the health service or call for assistance directly from the emergency services. The above condition raises the question of the logic and legitimacy of the indicated organization of pharmacies' duty hours and is the basis for the formulation of convictions according to which "multiple patient journeys between their inhabited places, a healthcare facility and a pharmacy which on a given day of duty is disadvantageous primarily for patients, as well as have no practical or economic justification" (Lower Silesian Pharmaceutical Chamber, 2016).

Pharmacy owners also claim that the county councils in the process of adopting the work schedule for generally accessible pharmacies do not consult with them, which in their opinion could contribute to the greater efficiency of these resolutions (Judgment of the Provincial Administrative Court in Poznań of 12.10.2017...).

The current legal status also raises objections on the part of county self-government bodies which are responsible for adopting the appropriate working hours schedules for generally accessible pharmacies. They point to the lack of legal regulations allowing the appropriate local council or other public administration body to enforce the implementation of the provisions of the adopted distribution by the concerned generally accessible pharmacies (Convention of Counties of the Łódź Voivodeship, 2017). Pharmaceutical law formulates in this respect only the regulation of art. 103 par. 2 point 3, according to which the voivodship pharmaceutical inspector may withdraw the authorization for operating a generally accessible pharmacy, if the pharmacy persistently does not satisfy the needs of the population in the scope of

dispensing medicinal products. With regard to the content of this provision, the Ministry of Health indicated, however, that “the above authority of the body should, however, be clearly separated from the issue of examining the non-compliance of a given pharmacy with the pharmacy work schedule set at the ‘powiat’ level, and possibly drawing specific consequences in this connection. No provision of the analysed Act explicitly provides for the obligation of pharmacies to comply with the work schedule established for them, nor does it provide for sanctions in this respect” (Ministry of Health, 2015).

In the content of the above-mentioned position of the Convention of Counties of the Łódź Voivodeship, it was also raised in the context of the wording of art. 94 par. 1 a.p.l., that “the editing of the regulation ordering the county (‘powiat’) council to impose working hours on pharmacies is not adapted to the real practice of performing the obligation imposed on pharmacies. In fact, the ‘powiat’ council does not develop a pharmacy work schedule, but the work of people employed in the pharmacy. The pharmacy is an entity, while work at night, on Saturdays, Sundays and public holidays applies to workers employed in the pharmacy and performed by them. The regulation made by the ‘Powiat’ Council each time interferes with employee relations, entering the competences of the employer, i.e. an entrepreneur conducting economic activity in the form of a pharmacy, obliged to organize working time in a way that would ensure correct settlement of employees’ working time, taking into account the statutory right to rest, and assuming that, by definition, overtime work is something special, anticipated in the event of the employer’s special needs” (Convention of Counties of the Łódź Voivodeship, 2017). It is therefore a reference to the arguments described above raised by representatives of the pharmacy community, indicating significant difficulties in ensuring the proper organization of work in the pharmacy in order to ensure the presence of professional staff during working hours resulting from the schedule adopted by the ‘powiat’ council. As part of the above position, it was also indicated that “the necessary analysis of the discussed provisions is required from the actual demand for the availability of the pharmaceutical service. It should be taken into account that satisfying emergency needs requiring urgent help and the possibility of obtaining medicine is strictly dependent on the availability of medical services correlated with the work of pharmaceutical facilities. In communities where there is a lack of 24-hour, all-night and holiday medical assistance, this assistance is provided only directly by medical emergency teams and ambulance physicians, and also as part of the ‘powiat’ medical centres on duty. In cities and communes in which there is no actual and real access to medical assistance, no pharmacy assistance is actually provided, as the rational choice of the pharmacy client is to purchase the prescription drug after medical consultation” (Convention of Counties of the Łódź Voivodeship, 2017). This position, indicating the need to make a purposive interpretation of the provision of art. 94 a.p.l. is largely consistent with the arguments raised by the pharmacy self-government. They indicate the need for such planning of

pharmacies' working hours schedule that would meet the real needs of the population and which are directly related to the availability of 24-hour medical assistance. In most cases, the urgent purchase of a medicinal product takes place after prior medical consultation.

4. Principles for determining the distribution of working hours of generally accessible pharmacies in light of the decisions of administrative courts

As a result, the abovementioned objections and doubts of the pharmaceutical environment and local government lead to appealing against the resolutions adopted by county councils regarding the establishment of the working hours of generally accessible pharmacies to the administrative courts. It is necessary to indicate here selected decisions of the administrative courts, in particular those referring to or related to the basic and most frequent arguments raised by the applicants, the significant spectrum of which has been discussed above.

Regarding the alleged breach of the principle of economic activity freedom by adopting local law imposing an obligation on individual pharmacies to work at specified times and days, the administrative courts take the view that this allegation is unjustified. According to the courts, the obligation of entrepreneurs operating generally accessible pharmacies to work within certain deadlines does not violate the essence of the constitutional principle of economic activity freedom. This obligation was imposed by law and is justified by the need to protect an important public interest, i.e. the protection of public health, which is correlated with the content of art. 22 and art. 31 par. 3 CRP. According to the content of art. 22, restrictions to the freedom of economic activity are permissible only by statute and only on grounds of important public interest. However, the content of art. 31 par. 3 CRP shows that restrictions regarding the use of constitutional freedom and rights may be established only by statute and only if they are necessary in a democratic state for its security or public order, or for the protection of the environment, public health and morality, or freedom and the rights of others. These limitations cannot violate the essence of constitutional freedom and rights. The Provincial Administrative Court in Gdańsk indicated in this regard that "the legislator has foreseen a situation when it will be necessary to graduate the protection of individual freedoms and civil rights. Health protection was mentioned among the goods that are subject to special protection that justifies the limitation of constitutional rights and civil liberties. Therefore, the restriction of civil liberties, including the freedom of economic activity, may occur if health protection requires it. It is important that the restriction of constitutional freedom should not violate its essence. Ensuring the availability of pharmaceutical services, including at night and on non-working days, falls within the concept of public health protection. The restriction of the freedom of economic activity

consisting in establishing a schedule of working hours of a generally accessible pharmacy does not violate the essence of this freedom. The entity operating such a pharmacy at the times specified in the schedule adopted by the ‘powiat’ council is not deprived of the possibility of conducting economic activity, but only suffers from certain restrictions in terms of pharmacy operation time” (Judgment of the Provincial Administrative Court in Gdańsk of 19.06.2019...).

Referring to the argument raised by representatives of the pharmacy community of the economic unprofitability of performing duty by generally accessible pharmacies, the voivodeship administrative courts take the view that this is a non-legal argument, not subject to any judicial review at all and, as a result, one that cannot constitute an effective premise for determining the unlawfulness of the contested resolution of the county (‘powiat’) council regarding the distribution of pharmacies’ working hours. The Supreme Administrative Court pointed out in this respect that “conducting economic activity in the form of pharmacies is the right and not the obligation of economic entities which, when undertaking it and obviously managing the economic account, must pay attention to the specificity of this activity and take into account the additional burdens that are connected with it” (Judgment of the Supreme Administrative Court of 14.12.2018...). The court also emphasized that “allegations of inaccuracy of the manner of implementing the provision of services used in the resolution proved to be unjustified because of little practical interest in all-night pharmacy services. Even individual cases of the necessity for the recipients to obtain medicinal products only available at the pharmacy justify the need for pharmacies night duty” (Judgment of the Supreme Administrative Court of 14.12.2018...).

It should also be mentioned that the Provincial Administrative Court in Bydgoszcz stated that “in relation to violation of labour law standards in terms of working time, it should be noted that it is the pharmacy managers who decide on the proper organization of the pharmacies work, which should not interfere with the employees working time and safety and occupational hygiene” (Judgment of the Provincial Administrative Court in Bydgoszcz of 30.08.2017...). A similar position was taken by the Provincial Administrative Court in Poznań, indicating that “performance of 24 hour, night and during non-working days duty falls within the scope of the statutory tasks of generally accessible pharmacies and the pharmacy manager should organize work so that the institution could fulfil this obligation” (Judgment of the Provincial Administrative Court in Poznań of 11.06.2014...). In the above-mentioned ruling of the Provincial Administrative Court in Gdańsk, it was stated, in turn, that “despite the fact that the profitability of conducting economic activity at night and during holidays may be questionable, nevertheless the entrepreneur operating a pharmacy is obliged to meet many legal requirements related to this activity and thus incur the costs of its conduct. It is also a matter of gradation of certain goods related to health protection in comparison with the economic calculation” (Judgment of the Provincial Administrative Court in Gdańsk of 19.06.2019...).

The administrative court rulings cited above, clearly show, that in the opinion of the courts every entity undertaking economic activity in running a generally accessible pharmacy must be aware of its specifics and legal requirements determining its performance and when planning the future economic account, pay attention to the need to perform its duty. None of the arguments indicating the economic and organizational difficulties related to this obligation, can constitute the legal basis for an effective objection regarding the legality of resolutions adopted in this matter by county councils.

Administrative courts also do not share the position raised by the pharmacy self-government, according to which schedules of public pharmacies' duty hours should be linked to the location and functioning of facilities providing medical services in a given county. For example, the Provincial Administrative Court in Łódź pointed out that "art. 94 par. 1 of the Pharmaceutical Law does not imply that determining the schedule of working hours of generally accessible pharmacies by the 'powiat' council was to take into account the hours of operation of medical facilities in that area. The availability of 24-hour medical care is another factor, and the need for the Council to provide 24-hour access to pharmacies in a powiat is another one. In a situation where people who need to buy only pharmaceuticals had to report each time at night and on Sundays and public holidays to medical facilities operating in the 'Powiat' [...], the patients who require medical assistance would have their access to this help significantly limited" (Judgment of the Provincial Administrative Court in Łódź of 19.04.2017...).

With regard to the last of the abovementioned allegations regarding the determination of the working hours of generally accessible pharmacies by county councils, i.e. the allegation of the lack of consultation on the part of county self-government bodies with the owners of generally accessible pharmacies during the resolution process, the administrative courts take the position that pursuant to art. 94 a.p.l. does not show that such an obligation was on the local council, and as a result, the lack of consultation cannot constitute the basis for the allegation that the resolution is not legally binding. In the content of art. 94 par. 2 a.p.l. the legislator provided for the obligation to carry out consultations only with the commune heads (mayors, city presidents) of communes from the county area and with the pharmacy self-government. As a consequence, failure to carry out consultations only to the extent required by the regulation of art. 94 par. 2 a.p.l. could be considered as a manifestation of a violation of the principle of legality in the process of adopting a resolution regarding the establishment of the work schedule of generally accessible pharmacies. The above connotation does not negate the possibility for powiat councils to consult also with pharmacy owners, however, such consultations cannot be considered as a duty of the powiat council. According to the position expressed in the judgment of the Provincial Administrative Court in Poznań, "The Poviatic Council may consult and take into account the position of pharmacy owners, but this is not required" (Judgment of the Provincial Administrative Court in Poznań of 12.10.2017...).

Concluding the analysis of the administrative court ruling in the scope of adopting resolutions by local councils regarding the distribution of working hours of generally accessible pharmacies, it should be noted that as part of the decisions taken, courts formulate specific guidelines addressed to ‘powiat’ self-government bodies in the scope of the premise which should be followed in the resolution process. The Provincial Administrative Court in Bydgoszcz pointed out that “when determining the distribution of pharmacies working hours, the ‘powiat’ council should take into account the ‘powiat’s’ conditions, such as: population, urban layout, density of housing, location of facilities providing medical services, communication between ‘powiat’ towns, access to public transport, access to infrastructure for people with disabilities” (Judgment of the Provincial Administrative Court in Bydgoszcz of 30.08.2017...). In addition, the court argued that “the minimum standard arising from the abovementioned provision is to ensure that at least one pharmacy in the count is open at all times,” the court stipulated that “it is obvious that there may be a need to establish more pharmacies on duty, especially in the case of counties with a large population” (Judgment of the Provincial Administrative Court in Bydgoszcz of 30.08.2017...).

5. *De lege ferenda* proposals for existing legal solutions

Considering the discussion of the spectrum of administrative court rulings, its conclusions should be referred to the content of the draft amendment to the Pharmaceutical Law Act developed by the Association of Polish Counties and the Supreme Pharmaceutical Council, which is based on the belief that in the absence of the possibility of neutralizing specific, perceived problems in the subject of determining the distribution of working hours of generally accessible pharmacies based on applicable regulations, perhaps achieving the expected and effective solutions is possible only by changing the Pharmaceutical Law.

On 1 June 2016, the 20th General Assembly of the Association of Polish Counties adopted a position on night duty by generally accessible pharmacies (General Assembly of the Association of Polish Counties, 2016). It states that the Association of Polish Counties in cooperation with the Supreme Pharmaceutical Council will undertake joint actions aimed at obtaining a compromise on the provision of night duty by generally accessible pharmacies. The effect of this cooperation was sending to the Minister of Health in February 2018 a draft amendment to the Pharmaceutical Law Act agreed by the Association of Polish Counties and the Supreme Pharmaceutical Council (Association of Polish Counties, 2018).

The basic change in relation to the current legal status is the proposal to finance the duty of generally accessible pharmacies by the National Health Fund. According to the content of the proposed art. 94d par. 1 a.p.l., an entity operating a generally accessible pharmacy, obliged on the basis of a duty schedule to perform the duty, is entitled to a flat-rate remuneration of 35 PLN per hour of duty, financed by the National Health Fund.

The project also assumes that the aforementioned duty plan (in place of the current distribution of pharmacies' working hours) would be adopted by the county council after consultation with the director of the provincial branch of the National Health Fund and after consulting the council of the pharmacy chamber.

An extremely important change referred to in the proposed art. 94 par. 2 a.p.l., is to shape the competences of the local council to determine the aforementioned duty plan, not on the basis of an obligation but only the possibility. According to the content of the proposed art. 94 par. 2 a.p.l., in order to provide access to pharmaceutical services at night, on Sundays, public holidays and other non-working days, the county council may, by resolution, establish a duty plan for generally accessible pharmacies, hereinafter referred to as "the duty plan". According to the content of the proposed art. 94 par. 3 a.p.l. the obligation of establishing the duty plan would rest with the council only if two conditions were met:

- data published by the Central Statistical Office indicate that the seat of the county is in a locality with no more than 40,000 residents;
- within the county there is a medical establishment providing services of night and holiday health care for the service provider referred to in art. 132b par. 1 of the Act of 27 August 2004 on the Act on healthcare services financed from public funds.

In accordance with the proposed art. 94b par. 2 a.p.l. when establishing the duty plan, the county council should take into account in particular:

- the needs of the local community regarding access to services provided by generally accessible pharmacies;
- the location of the pharmacy, including the distance from medical centres where night and holiday health care services are provided within the meaning of art. 5 point 17a of the Act on healthcare services financed from public funds.

In addition, according to the content of the proposed art. 94b par. 3 a.p.l., the duty plan should be set in such a way that no more than two generally accessible pharmacies are on duty at the same time.

The discussed project also provides, in accordance with the content of the proposed wording of art. 94c par. 3 a.p.l. that the county council could, by way of a resolution, depart from determining the duty plan if the opinion of the District Council of the Pharmaceutical Chamber containing a detailed analysis of the situation in a given county indicates that none of the generally accessible pharmacies operating in the county is able to perform their duty because there are not enough pharmacists.

The draft amendment to the Act – Pharmaceutical Law and some other acts agreed and submitted by the Association of Polish Counties and the Supreme Pharmaceutical Council certainly constitute an important voice in the discussion on the functioning and organization of the duty system of generally accessible pharmacies. The concept of introducing a flat-rate payment for pharmacies on duty meets the expectations of the pharmacy community and is – although not on a full scale – an attempt to reflect in the Polish legal system the solutions adopted in 2013

in Germany as part of the reimbursement system for night duty of pharmacies (Department of Foreign Affairs of the Supreme Pharmaceutical Council). Under the German system, a special purpose fund was created, managed by the Association of German Pharmacists, from which a flat-rate fee is paid to pharmacies for their duty hours. The amount of the payment is independent of the number of patients and is payable directly on account of the pharmacy duty. A very important issue is the fact that the resources of the afore-mentioned fund come from increasing the fixed fee for each package of prescription medicine issued by the pharmacy. Settlements of refunds are made on a quarterly basis upon the information supplied to the fund by pharmacies about the number of prescription drug packages issued in a given quarter and the number of night duties.

To conclude the considerations on the draft amendment to the Act – Pharmaceutical Law and some other acts agreed by the Association of Polish Counties and the Supreme Pharmaceutical Council, it should be noted that some of the proposed solutions appear to be in opposition to the beliefs, concepts and indications expressed in the content of the cited administrative court rulings.

First of all, according to the position taken by administrative courts, health protection is one of the most important categories of public interest, therefore state administration bodies and local government bodies should make every effort to ensure the strictest and most effective protection of public health. Based on this assumption, the courts are of the opinion that the organization of the pharmacy work “the distribution of working hours should be adapted to the current, everyday needs of the population for common services provided by generally accessible pharmacies, provided in ordinary conditions, and must not ignore extraordinary situations which the frequency of occurrence is unpredictable, it is about determining such distribution of working hours of generally accessible pharmacies, which will create the option of the best and fastest possible use of the necessary assistance when there is no daily working hours of pharmacies, and there is an extraordinary, unpredictable need for drug administration. Because the legislator used the term “also at night” – accessibility should be 24 hours a day, because only then will the desirable condition from the social point of view arise for the best and quickest use of the necessary assistance, when the pharmacies daily working hours do not apply, and there is an extraordinary and unpredictable need for drug administration” (Judgment of the Supreme Administrative Court of 14.04.2015...). What is particularly important is that all economic and organizational arguments are considered by the courts to be non-legal and in fact cannot constitute grounds for excluding the obligation to ensure full access to services provided by generally accessible pharmacies.

In addition, it should be pointed out that the draft amendment to the Act – Pharmaceutical Law and certain other acts agreed by the Association of Polish Counties and the Supreme Pharmaceutical Council still has no legal solutions enabling the county council to effectively enforce fulfilling the obligation of the pharmacy to perform their duty in accordance with the adopted plan, and whose need for implementation is one of the important arguments in the on-going discussion.

At this point it should be indicated that the Ministry of Health still maintains its position, according to which it does not provide for the possibility of limiting the obligation of pharmacies to perform their duty (Ministry of Health, 2017). The Ministry of Health also indicates that the legislator has assigned pharmacies, as health care institutions, a special role related to a certain type of public mission. In view of the above, both the argument relating to the disproportion and lack of profitability of turnover carried out by pharmacies at night time, as well as the argument of difficulties in providing adequate pharmacy professional staff, cannot result in the failure to fulfil this mission.

6. Conclusion

Ensuring access to services provided by generally accessible pharmacies, also at night and on public holidays is a very important element of the organization of the healthcare system. The special role of pharmacies highlighted in the ruling of administrative courts and associated with restrictions on the freedom of establishment are a fact and it is difficult to argue with them. Nevertheless, it is very important to take all possible measures to ensure the effective functioning of the healthcare system, including the activities of pharmacies within the hours adopted by the county ('powiat') self-government authorities. Meanwhile, the current legal status does not ensure the required effectiveness and efficiency in this respect.

The joint proposal of the Association of Polish Counties and the Supreme Pharmaceutical Council discussed above constitutes an important and necessary voice in the discussion, but it also contains elements that are difficult to reconcile with the system of rules emerging from the uniform case law of the administrative courts, and as such can be seen as a contribution to further work. Due to the fact that performing their duties is an important element of the functioning of the healthcare system, the proposed possibility of not adopting the duty plan raises particular doubt, especially in the situation when the basis for this would be the inability to provide a sufficient number of pharmacists by any pharmacy in a given county. The administrative court rulings clearly show that such an argument (which in light of the currently applicable provisions of the Pharmaceutical Law is not legal) cannot outweigh the public goal of health protection. On the other hand, the proposal contained in the discussed project, to grant generally accessible pharmacies additional flat-rate remuneration for their duties, is crucial. In order to ensure the effective functioning of the health care system, it is impossible to completely omit the arguments raised by the pharmacy community that indicate the economic and organizational difficulties related to the implementation of this obligation.

Given the above, it seems that the proposed legal solutions should, on the one hand, head in the direction of searching for sources of financing of the mandatory

operation of pharmacies required by law, while on the other, what is missing in the discussed project, provide county self-government bodies with a legally effective possibility of enforcing the obligation of pharmacies to perform their duty.

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